REMARKS

Claims 1-27 are pending, claims 11-25 standing withdrawn following a restriction requirement, and claims 1-10 and 26-27 have been rejected on various grounds, as will be discussed below.

Applicants have amended claims 1 and 6. Applicants have not added any claims and have canceled claims 4 and 10. Accordingly, claims 1-3, 5-9, and 26-27 are now present for examination.

In view of the following discussion, applicants respectfully request that the Examiner reconsider and withdraw the rejections made in the outstanding Office Action.

Support for the Amendments

Applicants have amended the claims in order to more clearly describe and distinctly claim the subject matter of applicants' crystalline Form Z of rabeprazole sodium and methods for preparing same. Specifically, applicants have canceled claim 4 and incorporated the subject matter therein into claims 1 and 6. Claims 1 and 6 now recite crystalline Form Z of rabeprazole sodium "having substantially the same X-ray diffraction pattern as shown in Figure 1."

Applicants have also canceled claim 10.

These amendments to the claims are fully supported in the specification as originally filed, and thus no new matter is introduced by these amendments in accordance with 35 U.S.C. § 132. Accordingly, applicants request entry of these amendments.

Rejection of Claims 1-10, 26 and 27 under 35 U.S.C. § 102(a), (b) and/or (e) as being anticipated by Takashi et al., Souda et al., and Reddy et al.

The Examiner has rejected claims 1-10 and 26-27 under 35 U.S.C. § 102(a), (b) and/or (e) as being anticipated by Japanese Patent Publication No. 2001-39975

(Takashi et al.), United States Patent No. 5,045,552 (Souda et al.) (example 33), and International Publication No. WO 03/082858 (Reddy et al.) (Formula 1). The Examiner states that Takashi et al., Souda et al., and Reddy et al. disclose the instant rabeprazole sodium salt. The Examiner states that many pharmaceutical solids exhibit polymorphism, which is frequently defined as the ability of a substance to exist as two or more crystalline phases that have different arrangements and/or conformations of the molecules in the crystal lattice, and thus polymorphs are different crystalline forms of the same pure substance in which the molecules have different arrangements and/or different conformations of the molecules. The Examiner argues that the term form Z does not offer any demarcation of the product from the prior art crystalline product. Applicants' claims, as amended, obviate the Examiner's rejections.

As set out above, applicants have canceled claim 4 and incorporated the subject matter therein into claims 1 and 6. Claims 1 and 6 now recite crystalline Form Z of rabeprazole sodium "having substantially the same X-ray diffraction pattern as shown in Figure 1."

The Takashi et al. reference discloses the structure of rabeprazole but the Takashi et al. reference is in Japanese and the Examiner cites no specific part of Takashi et al. disclosing the crystallization of rabeprazole.

The Souda et al. reference discloses in example 33 the crystallization of the sodium salt of rabeprazole from ether.

The Reddy et al. reference discloses a process for preparing Form X of rabeprazole sodium comprising dissolving rabeprazole in a C_1-C_4 alkanol of sodium hydroxide; distilling the solvent from the reaction solution; adding a chlorinated C_1-C_3 hydrocarbon solvent to the residual mass; distilling the residual solvent of C_1-C_4 alkanol of sodium hydroxide from the reaction solution; adding a chlorinated C_1-C_3 hydrocarbon solvent and a C_5-C_{10} alkane solvent or a C_5-C_{10} cyclic alkane with stirring, and isolating Form X of rabeprazole sodium.

The Reddy et al. reference also discloses a process for preparing Form Y of rabeprazole sodium comprising dissolving rabeprazole in a C_1-C_4 alkanol of sodium hydroxide; distilling the solvent from the reaction solution; optionally adding a

chlorinated C_1-C_3 hydrocarbon solvent to the residual mass; distilling the residual solvent of C_1-C_4 alkanol of sodium hydroxide from the reaction solution; adding to the residue a C_3-C_5 straight or branched chain alcohol and an ether solvent with stirring; and isolating Form Y of rabeprazole sodium.

Applicants' process for making crystalline Form Z of rabeprazole sodium comprises admixing rabeprazole sodium in an aromatic hydrocarbon solvent, heating the aromatic hydrocarbon solvent to reflux, and cooling the solvent until a solid mass of crystalline Form Z of rabeprazole sodium separates. Applicants' specification at claim 18.

Applicants submit that Takashi et al., Souda et al., and Reddy et al. do not anticipate applicants' claims, as amended, for preparing crystalline Form Z of rabeprazole sodium. Takashi et al. is in Japanese and the Examiner cites no specific part of Takashi et al. disclosing the crystallization of rabeprazole. Souda et al. discloses the crystallization of rabeprazole sodium from ether. Reddy et al. discloses preparing Form X of rabeprazole sodium by dissolving rabeprazole in a C_1-C_4 alkanol of sodium hydroxide, distilling the solvent, adding a chlorinated C_1-C_3 hydrocarbon solvent, distilling the residual solvent of C_1-C_4 alkanol of sodium hydroxide, adding a chlorinated C_1-C_3 hydrocarbon solvent and a C_5-C_{10} alkane solvent or a C_5-C_{10} cyclic alkane with stirring, and isolating Form X of rabeprazole sodium. Reddy et al. also discloses preparing Form Y of rabeprazole sodium by dissolving rabeprazole in a C_1-C_4 alkanol of sodium hydroxide, distilling the solvent, optionally adding a chlorinated C_1-C_3 hydrocarbon solvent, distilling the residual solvent of C_1-C_4 alkanol of sodium hydroxide; adding to the residue a C_3-C_5 straight or branched chain alcohol and an ether solvent with stirring, and isolating Form Y of rabeprazole sodium. Applicants' process for making crystalline Form Z of rabeprazole sodium comprises admixing rabeprazole sodium in an aromatic hydrocarbon solvent, heating the aromatic hydrocarbon solvent to reflux, and cooling the solvent until crystalline Form Z of rabeprazole sodium separates. Takashi et al., Souda et al., and Reddy et al. do not teach to prepare crystalline Form Z of rabeprazole sodium by heating to reflux rabeprazole sodium in an aromatic hydrocarbon and cooling the solvent until crystalline Form Z of rabeprazole

sodium separates. Rather, Souda et al. crystallizes the sodium salt of rabeprazole from ether and Reddy et al. precipitates the sodium salt of rabeprazole from a chlorinated C_1-C_3 hydrocarbon solvent and a C_5-C_{10} alkane solvent or a C_5-C_{10} cyclic alkane; or a C_3-C_5 straight or branched chain alcohol and an ether solvent.

Takashi et al., Souda et al., and Reddy et al. also do not disclose applicants' crystalline Form Z of rabeprazole sodium having substantially the same X-ray diffraction pattern as shown in Figure 1.

In summary, Takashi et al., Souda et al., and Reddy et al. do not teach each and every element of applicants' crystalline Form Z of rabeprazole sodium. Accordingly, Takashi et al., Souda et al., and Reddy et al. do not anticipate applicants' claims under 35 U.S.C. § 102(b).

Polymorphs arise when molecules of a compound arrange in the solid state in distinct ways. By varying the temperature of the solution and using different solvents, different polymorphs can be formed. Although identical in chemical composition, polymorphs can have very different properties. Polymorphs are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns.

Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art. Akzo N.V. v. U.S. International Trade Commission, 1 USPQ 2d 1241, 1245 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987). Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). We think the precise language of 35 U.S.C. §102 that "a person shall be entitled to a patent unless," concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under §102 and §103. In re Warner, 154 USPQ 173, 177 (C.C.P.A. 1967), cert. denied, 389 U.S. 1057 (1968).

Hence, the Examiner's rejection of claims 1-10 and 26-27 under 35 U.S.C. § 102(a), (b) and/or (e) as being anticipated by Takashi et al., Souda et al., and Reddy et al. should be withdrawn.

Rejection of Claims 1-10 and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over Takashi et al., Souda et al., and Nochi et al. in view of Haleblian et al., Brittain et al., Muzaffar et al., Jain et al., Chemical & Engineering News, US Pharmacopia, and Concise Encyclopedia Chemistry.

The Examiner has rejected claims 1-10 and 26-27 under 35 U.S.C. §103(a) as being unpatentable over Takashi et al., Souda et al., and Nochi et al. in view of J. of Pharm. Sciences, (1969), 58, pp 911-929 (Haleblian et al.); Polymorphism in Pharmaceutical Solids, NY Marcel Dekker, Inc. 1999, pp. 228-361 (Brittain et al.); J. of Pharmacy (Lahore) 1979, 1(1), 59-66 (Muzaffar et al.); Indian Drugs, 1986,23 (6) 315-329 (Jain et al.); Chemical & Engineering News, Feb. 2003 (C&E News); US Pharmacopia, 1995, pp. 1843-1844 (USP); and Concise Encyclopedia Chemistry, pages 872-873 (1993) (CEC). The Examiner states that Takashi et al., Souda et al. (examples 32 and 33), and Nochi et al. (Formula 1) disclose the instant rabeprazole sodium salt and the process for making same. The Examiner further states that Muzaffar et al. (page 60), Brittain et al., Jain et al., and Haleblian et al. teach that compounds can exist in different crystalline forms. The Examiner argues that C&E News, USP, and CEC teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. The Examiner concludes that the claimed crystalline form as well as its relative selectivity of properties vis-à-vis the known compound are suggested by the references and it would be obvious in view of the references that the instant compound would exist in different crystalline forms. Applicants' claims, as amended, obviate the Examiner's rejection.

The Examiner states that motivation to produce the compounds encompassed by the claims is not abstract but is related to the properties or uses that one having ordinary skill in the art would have expected the resulting compound to exhibit. The

Examiner argues that in situations involving chemical compounds bearing a close similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties.

As set out above, applicants have canceled claim 4 and incorporated the subject matter therein into claims 1 and 6. Claims 1 and 6 now recite a crystalline Form Z of rabeprazole sodium "having substantially the same X-ray diffraction pattern as shown in Figure 1."

The Takashi et al. reference discloses the structure of rabeprazole but the Takashi et al. reference is in Japanese and the Examiner cites no specific part of Takashi et al. disclosing the crystallization of rabeprazole.

The Souda et al. reference discloses rabeprazole. In Example 32, Souda et al. crystallizes rabeprazole from dichloromethane/ether and in Example 33, Souda et al. crystallizes rabeprazole from ether.

The Nochi et al. reference discloses crystallizing rabeprazole from ether/hexane.

The Haleblian et al. and Jain et al. references state that polymorphism is the ability of any compound to crystallize as more than one distinct crystal species and different polymorphs of a given compound are, in general, as different in structure and properties as the crystals of two different compounds. Haleblian et al. and Jain et al. state that solubility, melting point, density, hardness, crystal shape, optical and electrical properties, vapor pressure, and the like, vary with the polymorphic form and it should be possible to obtain different crystal forms of a drug with different performance properties. (Haleblian et al. at p. 911, col. 2, top paragraph and Jain et al. at p. 315, col. 2).

The Muzaffar et al. reference states that about one in every three organic compounds exhibits polymorphic behavior. The differences are primarily in crystalline structure which give rise to different physical properties. The molecules of drugs exhibit different space-lattice arrangements in the crystal form from one polymorph to the other, and have different physical properties such as density, melting point, dissolution rate, solubility, hardness, crystal shape, crystal habit, friability, and optical properties. (Muzaffar et al. at p. 60, middle paragraph).

The Brittain et al reference discloses various analytical methodologies used to characterize polymorphic solids. C&E News, USP, and CEC merely teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable.

Applicants' process for making crystalline Form Z of rabeprazole sodium comprises admixing rabeprazole sodium in an aromatic hydrocarbon solvent, heating the aromatic hydrocarbon solvent to reflux, and cooling the solvent until a solid mass of crystalline Form Z of rabeprazole sodium separates. Applicants' specification at claim 18.

Applicants submit that the present claims, as amended, are not obvious over Takashi et al., Souda et al., and Nochi et al. in view of Haleblian et al., Brittain et al., Muzaffar et al., Jain et al., C&E News, USP, and CEC. Takashi et al. is in Japanese and the Examiner cites no specific part of Takashi et al. disclosing the crystallization of rabeprazole. Souda et al. discloses the crystallization of rabeprazole from ether or dichloromethane/ether. Nochi et al. discloses crystallizing rabeprazole from ether/hexane. Applicants' process for making crystalline Form Z of rabeprazole sodium comprises admixing rabeprazole sodium in an aromatic hydrocarbon solvent, heating the aromatic hydrocarbon solvent to reflux, and cooling the solvent until crystalline Form Z of rabeprazole sodium separates. Takashi et al., Souda et al., and Nochi et al. do not teach to prepare crystalline Form Z of rabeprazole sodium by heating to reflux rabeprazole sodium in an aromatic hydrocarbon and cooling the solvent until crystalline Form Z of rabeprazole sodium separates. Rather, Souda et al. crystallizes the sodium salt of rabeprazole from ether or dichloromethane/ether and Nochi et al. crystallizes rabeprazole from ether/hexane.

Takashi et al., Souda et al., and Nochi et al. also do not disclose applicants' crystalline Form Z of rabeprazole sodium having substantially the same X-ray diffraction pattern as shown in Figure 1.

The secondary references of Haleblian et al., Brittain et al., Muzaffar et al., Jain et al., C&E News, USP, and CEC add nothing to the primary references of Takashi et al., Souda et al., and Nochi et al.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972. 973 (Bd. Pat. App. & Inter. 1985). MPEP 706.02(j)

Obviousness of a composition or process must be predicated on something more than it would be obvious "to try" the particular component recited in the claims or the possibility it will be considered in the future, having been neglected in the past. Ex parte Argabright et al. (POBA 1967) 161 USPQ 703. There is usually an element of "obvious to try" in any research endeavor, since such research is not undertaken with complete blindness but with some semblance of a chance of success. "Obvious to try" is not a valid test of patentability. In re Mercier (CCPA 1975) 515 F2d 1161, 185 USPQ 774; Hybritech Inc. v. Monoclonal Antibodies. Inc. (CAFC 1986) 802 F2d 1367, 231 USPQ 81; Ex parte Old (BPAI 1985) 229 USPQ 196; In re Geiger (CAFC 1987) 815 F2d 686, 2 USPQ2d 1276. In re Dow Chemical Co. (CAFC 1988) F2d, 5 USPQ2d 1529. Patentability determinations based on that as a test are contrary to statute. In re Antonie (CCPA 1977) 559 F2d 618, 195 USPQ 6; In re Goodwin et al. (CCPA 1978) 576 F2d 375, 198 USPQ 1; In re Tomlinson et al. (CCPA 1966) 363 F2d 928, 150 USPQ 623. A rejection based on the opinion of the Examiner that it would be obvious

to try the chemical used in the claimed process which imparted novelty to the process does not meet the requirement of the statute (35 U.S.C. 103) that the issue of obviousness be based on the subject matter as a whole. In re Dien (CCPA 1967) 371 F2d 886, 152 USPQ 550; In re Wiaains (CCPA 1968) 397 F2d 356, 158 USPQ 199; In re Yates (CCPA 1981) 663 F2d 1054, 211 USPQ 1149. Arguing that mere routine experimentation was involved overlooks the second sentence of 35 USC 103. In re Saether (CCPA 1974) 492 F2d 849,181 USPQ 36. The issue is whether the experimentation is within the teachings of the prior art. In re Waymouth et al. (CCPA 1974) 499 F2d 1273, 182 USPQ 290. The fact that the prior art does not lead one skilled in the art to expect the process used to produce the claimed product would fail does not establish obviousness. In re Dow Chem. Co. (CAFC 1988) 5 USPQ2d 1529.

The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggest to one of ordinary skill in the art. The references of record fail to teach or suggest applicant's invention as a whole.

Hence, the Examiner's rejection of claims 1-10 and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over Takashi et al., Souda et al., and Nochi et al. in view of Haleblian et al., Brittain et al., Muzaffar et al., Jain et al., C&E News, USP, and CEC should be withdrawn.

Rejection of Claims 1-10 and 26-27 under 35 U.S.C. § 112, first paragraph.

The Examiner has rejected claims 1-10 and 26-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. However, processes for the preparation of the claimed form of rabeprazole is described in a detailed manner in the applicants' examples.

The Examiner states that there is a lack of description as to whether the compositions are able to maintain the compound in the crystalline form claimed. The

Examiner asserts that processing a compound into a pharmaceutical composition could create a different form than the crystalline form being claimed or even back to the compound itself. The Examiner states that disclosure of X-ray diffraction patterns for pharmaceutical compositions comprising the crystalline forms are lacking in the specification and the X-ray diffraction patterns and differential scanning calorimetry thermogram only supports the crystalline Form Z of rabeprazole sodium.

The Examiner states that there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands. 858 F.2d 731, 737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants traverse the Examiner's rejection.

The Examiner states that polymorphs may undergo transformation when being formulated into pharmaceutical compositions but polymorphism and crystallization may be mastered from start to finish. The Examiner's position that applicants' polymorphs may undergo transformation when being formulated into compositions is speculation.

Applicants' specification need describe the invention only in such detail as to enable a person skilled in the most relevant art to make and use it. When an invention involves distinct arts, that specification is adequate which enables the adepts of each art, those who have the best chance of being enabled, to carry out the aspect proper to their specialty.

> The question is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 USPQ 481, 489 (Fed. Cir. 1984)
>
> It has been consistently held that the first paragraph of 35 U.S.C. §112 required nothing more than objective enablement... In satisfying the

> enablement requirement, as application need not teach, and preferably omits that which is well-known in the art.....How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support. .
>
> The error we see in Staehelin's approach to the question before us is that Staehelin would require a patent specification to be a blueprint, which, if followed, would unfailingly reproduce exactly an applicant's claimed invention. However, the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 U.S.C. §112, first paragraph. Staehelin v. Secher, 24 USPQ 2d 1513, 1516 (B.P.A.I. 1992)

Hence, the Examiner's rejection of claims 1-10 and 26-27 under 35 U.S.C. §112, first paragraph, should be withdrawn.

Rejection of Claims 1-10 and 26-27 under 35 U.S.C. §112, second paragraph.

The Examiner has rejected claims 1-10 and 26-27 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that claims 2-5, 26, and 27 lack antecedent basis for the recited limitations. The Examiner states that claim 1 does not permit the sodium forms or set forth the properties recited in the dependent claims and claim 1 does not specify any X-ray powder diffraction patterns for the instant sodium forms. The Examiner further argues that the expression "substantially the same" in claim 4 is indefinite to its meaning. The Examiner states that the term Form Z in claims 1 and 7-10 is a universal identification of compounds but the terms Crystal II, Form X and Form Y do not define specific compounds. The Examiner states that claims 1 and 6-10 contain the trademark/trade name rabeprazole, which does not comply with the requirements of 35 U.S.C. §112, second paragraph. The Examiner further argues that the notation of Form Z of rabeprazole sodium is not a universal identification of the compound. The Examiner states that claims 4 and 26 are incomplete because the claims are not self-contained in particularly pointing out and

distinctly claiming what applicants regard as their invention. Applicants traverse in part the Examiner's rejections and applicants' claims, as amended, obviate in part the Examiner's rejections.

The Examiner states that claims 2-5, 26, and 27 lack antecedent basis for the recited limitations and claim 1 does not permit the sodium forms recited in the dependent claims and claim 1 does not specify any X-ray powder diffraction patterns for the instant sodium forms.

As set out above, applicants have canceled claim 4 and incorporated the subject matter therein into claims 1 and 6. Claims 1 and 6 now recite crystalline Form Z of rabeprazole sodium "having substantially the same X-ray diffraction pattern as shown in Figure 1."

Accordingly, claims 1-5, 26, and 27, as amended, do have antecedent basis and the Examiner's rejection should be withdrawn.

The Examiner states that the expression "substantially" in claim 4 is indefinite to its meaning. Applicants traverse the Examiner's rejections.

> Another important principle is that an applicant will be afforded a great amount of latitude in formulating his claims in the manner, which he deems to most adequately define his invention. In re Duva, 156 USPQ 90 (C.C.P.A. 1968). In this regard, an applicant may use either conventional terms, or he may be his own lexicographer, as long as the meaning is clear. In re Castaing, 166 USPQ 550 (C.C.P.A. 1970). An applicant may leave room open for experimental error by using such words as "substantially", "approximately" or the like, without rendering his claims indefinite. In re Mattison, 184 USPQ 484 (C.C.P.A. 1975}; Ex parte Sobin, 139 USPQ 528 (P.O.Bd. App. 1962); Ex parte Shea, 171 USPQ 383 (P.O.Bd. App. 1971). Claims are to be read in light of the specification, particularly for the purpose of interpreting the meaning of words used by the applicant. In re Okuzawa, 190 USPQ 464 (C.C.P.A. 1976). Cf: In re Herz, 190 USPQ 461 (C.C.P.A. 1976). Cf: In re Merat, 186 USPQ 471 (C.C.P.A. 1975).

Accordingly, the expression "substantially" in claim 4 is definite to its meaning and there is sufficient antecedent basis for the limitations.

The Examiner states that the term Form Z in claims 1 and 7-10 is a universal identification of compounds but the terms Crystal II, Form X and Form Y do not define specific compounds.

As set out above, applicants have canceled claim 10. Accordingly, the Examiner's rejection of claim 10 should be withdrawn.

The Examiner states that claims 1 and 6-10 contain the "trademark/trade name" rabeprazole, which does not comply with the requirements of 35 U.S.C. § 112, second paragraph. Applicants' claims traverse the Examiner's rejections.

Applicants have described the structure of rabeprazole sodium in applicants' specification as follows:

> Rabeprazole sodium, 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfonyl]-1H-benzimidazole sodium is an inhibitor of the gastric proton pump. It belongs to a class of anti secretory compounds that do not exhibit anticholinergic or histamine H2-receptor antagonist properties, but suppress gastric acid secretion by inhibiting the gastric H+, K+ ATPase at the secretory surface of the gastric parietal cell. Rabeprazole blocks the final step of gastric acid secretion. Applicants' specification at page 1, first full paragraph.

Moreover, Reddy et al., which the Examiner has cited against applicants, recites as follows:

Achiphex7 (rabeprazole sodium) is an inhibitor of the gastric proton pump. It causes dose-dependant inhibition of acid secretion and is useful as an antiulcer agent. The chemical designation of rabeprazole sodium is 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridine-2-yl]-methyl] sulfinyl]-1H-benzimidazole sodium.

Rabeprazole is not a trademark or a trade name, but is an adopted name promulgated by the United States Adopted Names ("USAN") Council, a joint effort of the American Medical Association, the U.S. Pharmacopeial Convention, Inc., and the American Pharmacists Association. These USAN adopted names are typically accepted by the U.S. Food and Drug Administration as the official names for drug compounds, and are required to be used in the labeling of branded and generic products sold in the U.S. that contain the drugs (see 21 C.F.R. §§ 299.4 and 299.5). Applicants are attaching a printout from the electronic edition of the FDA's Orange Book

regarding rabeprazole, showing that the commercially available product has the active ingredient rabeprazole sodium, and is sold using the "proprietary name" ACIPHEX.

Accordingly, the generic term "rabeprazole sodium" does comply with the requirements of 35 U.S.C. § 112, second paragraph, and the Examiner's objection to claims 1 and 6-10 should be withdrawn.

The Examiner further argues that the notation of Form Z of rabeprazole sodium is not a universal identification of the compound.

As set out above, applicants have canceled claim 4 and incorporated the subject matter therein into claims 1 and 6. Claims 1 and 6 now recite crystalline Form Z of rabeprazole sodium "having substantially the same X-ray diffraction pattern as shown in Figure 1."

Hence, the notation of Form Z of rabeprazole sodium is clear. Accordingly, the notation of Form Z of rabeprazole sodium does comply with the requirements of 35 U.S.C. § 112, second paragraph, and the Examiner's objection to the claims should be withdrawn.

The Examiner further states that claims 4 and 26 are incomplete because the claims are not self-contained. Applicants assume that the Examiner is objecting to the reference to Figures 1 and 2.

First, the Examiner cites no support for this position. Second, as set out above, an applicant may be his own lexicographer, as long as the meaning is clear. Although identical in chemical composition, polymorphs can have very different properties and are distinguishable by various analytical techniques, especially X-ray powder diffraction patterns. The references to the X-ray powder diffraction pattern data and differential scanning calorimetry curve data in Figures 1-2 are very clear. Hence, claims 4 and 6 are complete and do comply with the requirements of 35 U.S.C. §112, second paragraph, and the Examiner's objection to the claims should be withdrawn.

Incorporating drawings that are X-ray diffraction patterns, infrared absorption spectra, or thermal analysis curves into claims is common in U.S. patents that have been granted for polymorphic forms of compounds. The patterns are entirely incapable

of being reduced into words, and therefore such incorporation is proper under Office policy.

Accordingly, the Examiner's rejection of claims 1-10 and 26-27 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Provisional Rejection of Claims 1-10 and 26-27 under the judicially created doctrine of Obviousness-type Double patenting as being unpatentable over Claims 1-13, 26 and 27.

The Examiner has provisionally rejected claims 1-10 and 26-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13, 26, and 27 of copending United States Patent Application No. 10/786,556 (however, since the present application is Application No. 10/786,556, applicants assume the Examiner intended to refer to Application No. 10/505,826) in view of Haleblian et al., Muzzaffar et al., Jain et al., Chemical & Engineering News, US Pharmacopia, Brittain et al, and Concise Encyclopedia Chemistry.

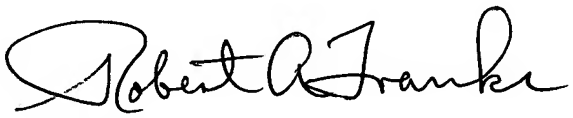
The Examiner states that this is a provisional obviousness-type double patenting rejection because serial no. 10/505,826 discloses crystal forms of the instant salts and the corresponding compositions and the ancillary references teach that the mere existence of further polymorphs of compounds is not in itself regarded as unexpected. The Examiner argues that patentable distinction is not seen. Applicants traverse the Examiner's provisional rejection.

Applicants submit that detailed discussion of this provisional double patenting rejection is not necessary or appropriate at this time because this rejection is only provisional since no claims have been allowed in either pending application. Moreover, the claims in both applications are still subject to amendment. The rejections are therefore only provisional because no claims have been allowed in the two copending patent applications and because no determination can be made whether the two sets of claims recite the same inventive concept or whether the two sets of claims are obvious variations of the same concept until these claims are in final form, M.P.E.P. § 804.

CONCLUSION

In view of the foregoing Amendment and Response, applicants request reconsideration pursuant to 37 C.F.R. § 112 and allowance of the claims pending in this application. Applicants request the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments, which might be most expeditiously handled by a telephone conference. No fee is deemed necessary in connection with the filing of this Response. If any fee is required, however, authorization is hereby given to charge the amount of such fee to Deposit Account No. 50-3221.

Respectfully submitted,



Robert A. Franks
Reg. No. 28,605
Attorney for Applicants

February 17, 2006

Dr. Reddy's Laboratories, Inc.
200 Somserset Corporate Blvd., Seventh Floor
Bridgewater, New Jersey 08807-2862
Telephone 908-203-6504
Facsimile 908-203-6515

Active Ingredient Search Results from "OB_Rx" table for query on "rabeprazole."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020973		Yes	RABEPRAZOLE SODIUM	TABLET, DELAYED RELEASE; ORAL	20MG	ACIPHEX	EISAI MEDCL RES

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
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Orange Book Data - **Monthly**

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Patent and Generic Drug Product Data Last Updated: February 14, 2006